PA 1272597

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

January 19, 2005

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: *10/838,648*
FILING DATE: *May 03, 2004*

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

TRUDIE WALLACE
Certifying Officer

Practitioner's Docket No. U 015177-0 *PATENT*

Preliminary Classification:
Proposed Class:
Subclass:
NOTE: "All applicants are requested to include a preliminary classification on newly filed patent applications. The preliminary classification, preferably class and subclass designations, should be identified in the upper right-hand corner of the letter of transmittal accompanying the application papers, for example 'Proposed Class 2, subclass 129.'" M.P.E.P. Section 601, 7th ed.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Mail Stop Patent Application
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Optional Customer No. Bar Code

00140
PATENT TRADEMARK OFFICE

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of
Inventor(s):

1. YOSSI GROSS
2. OZ CABIRI
3. BORIS DEGTIAR
4. ERAN SHOR

WARNING: *37 C.F.R. Section 1.41(a)(1) points out:*

"(a) A patent is applied for in the name or names of the actual inventor or inventors.

(1) The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by Section 1.63, except as provided for in Section 1.53(d)(4) and Section 1.63(d). If an oath or declaration as prescribed by Section 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to Section 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in Section 1.17(l) is filed supplying or changing the name or names of the inventor or inventors."

For (title): PRESSURE-PROPELLED SYSTEM FOR BODY LUMEN

CERTIFICATION UNDER 37 C.F.R. 1.10*
(Express Mail label number is mandatory.)
(Express Mail certification is optional.)

I hereby certify that this correspondence and the documents referred to as attached therein are being deposited with the United States Postal Service on this date May 3, 2004 in an envelope as "Express Mail Post Office to Addressee", mailing Label Number EV 481668080 US, addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450

GERALDINE MARTI
(type or print name of person mailing paper)

Geraldine Marti
Signature of person mailing paper

WARNING: *Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.*

**WARNING:* *Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).*
"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

EXPRESS MAIL LABEL

1. Type of Application

This new application is for a(n)

(check one applicable item below)

[X] Original (nonprovisional)
[ ] Design
[ ] Plant

WARNING: ***Do not use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. 371(c)(4), unless the International Application is being filed as a divisional, continuation or continuation-in-part application.***

WARNING: ***Do not use this transmittal for the filing of a provisional application.***

NOTE: If one of the following 3 items apply, then complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED and a NOTIFICATION IN PARENT APPLICATION OF THE FILING OF THIS CONTINUATION APPLICATION.

[ ] Divisional.
[ ] Continuation.
[ ] Continuation-in-part (C-I-P).

2. Benefit of Prior U.S. Application(s) (35 U.S.C. Sections 119(e), 120, or 121)

NOTE: ***A nonprovisional application may claim an invention disclosed in one or more prior filed copending nonprovisional applications or copending international applications designating the United States of America. In order for a nonprovisional application to claim the benefit of a prior filed copending nonprovisional application or copending international application designating the United States of America, each prior application must name as an inventor at least one inventor named in the later filed nonprovisional application and disclose the named inventor's invention claimed in at least one claim of the later filed nonprovisional application in the manner provided by the first paragraph of 35 U.S.C. Section 112. Each prior application must also be:***

(I) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or

(ii) Complete as set forth in Section 1.51(b); or

(iii) Entitled to a filing date as set forth in Section 1.53(b) or Section 1.53(d) and include the basic filing fee set forth in Section 1.16; or

(iv) Entitled to a filing date as set forth in Section 1.53(b) and have paid therein the processing and retention fee set forth in Section 1.21(l) within the time period set forth in Section 1.53(f).

37 C.F.R. Section 1.78(a)(1).

WARNING: ***If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. §§120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. §§ 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. §§ 119, 365(a) or 365(b).) For a C-I-P application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.***

WARNING: *37 C.F.R. § 1.78(a)(2) deals with the time in which the claim for the benefit of an earlier filing date must be made and states:*

"(2)(i) Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application or international application designating the United States of America claiming the benefit of one or more prior-filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain a reference to each such prior-filed application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Cross references to other related applications may be made when appropriate (see § 1.14).

(ii) This reference must be submitted during the pendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C. 111(a)(, this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed application. If the later0filed application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, this reference must also be submitted within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f)(in the later-filed international application sixteen months from the filing date of the prior-filed application. These time periods are not extendable. Except as provided in paragraph (a)((3)(of this section, the failure to timely submit the reference required by 35 U. S. C 120 and paragraph (a)(2)(i) of this section is considered a waiver of any benefit under 35 U.S.C. 120, 121, or 365(c) to such prior-filed application. The time periods in this paragraph do not apply if the later-filed application is:

(A) An application for a design patent;

(B) An application filed under 35 U.S.C. 111(a) before November 29, 2000; or

(C) A nonprovisional application which entered the national stage after compliance with 35U.S.C. 371 from an international application filed under 35 U.S.C. 363 before November 29, 2000..

(iii) If the later-filed application is a nonprovisional application, the reference required by this paragraph must be included in an application data sheet (§ 1.76), or the specification must contain or be amended to contain such reference in the first sentence following the title.

(iv) The request for a continued prosecution application under § 1.53(d) is the specific reference required by 35 U.S.C. 120 to the prior-filed application. The identification of an application by application number under this section is teg identification of every application assigned that application number necessary for a specific reference required by 35 U.S.C. 120 to every such application assigned that application number."

NOTE: *If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., or benefit of a prior provisional application is claimed, then check the following item and complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.*

[X] The new application being transmitted claims the benefit of prior U.S. application(s). Enclosed are ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

3. Papers Enclosed

A. Required for Filing Date under 37 C.F.R. Section 1.53(b) (Regular) or 37 C.F.R. Section 1.153 (Design) Application

__27__ Pages of Specification
__11__ Pages of Claims
__6__ Sheets of Drawing

WARNING: ***DO NOT*** *submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to Section 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. For comments on proposed then-new 37 C.F.R. 1.84, see Notice of March 9, 1988. (1990 O.G. 57-62).*

NOTE: "Identification of drawings. Identifying indicia, if provided, should include the title of the invention, inventor's name and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin."

(complete the following, if applicable)

[ ] The enclosed drawing(s) are photograph(s).

NOTE: 37 C.F.R. 1.84
"(b) Photographs.

"(1) Black and white. Photographs, including photocopies of photographs, are not ordinarily permitted in utility and design patent applications. The Office will accept photographs in utility and design patent applications, however, if photographs are the only practicable medium for illustrating the claimed invention. For example, photographs, or photomicrographs of: electrophoresis gels, blots (e.g., immunological, western, Southern and northern), auto radiographs, cell cultures (stained and unstained), histological tissue cross sections (stained and unstained), animals, plants, in vivo imaging, thin layer chromatography plates, crystalline structures, and in a design patent application, ornamental effects, are acceptable. If the subject matter of the application admits of illustration by a drawing, the examiner may require a drawing in place of the photograph. The photographs must be of sufficient quality so that all details in the photographs are reproducible in the printed patent.

"(2) Color photographs. Color photographs will be accepted in utility and design patent applications if the conditions for accepting color drawings and black and white photographs have been satisfied. See paragraphs (a)(2) and (b)(1) of this section."

[ ] The enclosed drawing(s) are in color. Three (3) sets of color drawings and a "PETITION TO ACCEPT COLOR DRAWING(S)" are attached. 37 C.F.R. §§ 1.84(a)(2) and 1.84(b).

NOTE: 37 C.F.R. 1.84(a)

"(2) Color. On rare occasions color drawings may be necessary as the only practical medium by which to disclose the subject matter sought to be patented in a utility or design patent application or the subject matter of a statutory invention registration. The color drawings must be of sufficient quality such that all details in the drawings are reproducible in black and white in the printed patent. Color drawings are not permitted in international applications (see PCT Rule 11.13), or in an application, or copy thereof, submitted under the Office electronic filing system. The Office will accept color drawings in utility or design patent applications and statutory invention registrations only after granting a petition filed under this paragraph explaining why the color drawings are necessary. Any such petition must include the following:

(i) The fee set forth in § 1.17(h);

(ii) Three (3) sets of color drawings;

(iii) A black and white photocopy that accurately depicts, to the extent possible, the subject matter shown in the color drawing; and

(iv) *An amendment to the specification to insert (unless the specification contains or has been previously amended to contain) the following language as the first paragraph of the brief description of the drawings:*

"The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee."

[x] Formal
[ ] Informal

B. Other Papers Enclosed

_____ Pages of declaration and power of attorney
__1__ Pages of Abstract
_____ Other

4. Additional Papers Enclosed

[ ] Preliminary Amendment
[ ] Information Disclosure Statement (37 C.F.R. Section 1.98)

WARNING: *In order to ensure consideration of information previously submitted but which has not been considered in the parent application, an applicant must resubmit the information, complying with 37 C.F.R. § 1.97 and 37 C.F.R. § 1.98, in the continuing application filed under 37 C.F.R. § 1.53(b). See § 609B(3), M.P.E.P., 7th Edition,* Rev. 1.

[ ] Form PTO-1449 (PTO/SB/08A and 08B)
[ ] Citations
[ ] Statement of Biological Deposit
[ ] Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence.
[ ] Authorization of Attorney(s) to Accept and Follow Instructions from Representative
[ ] Special Comments
[ ] Request for Nonpublication of Application
[ ] Other

5. Declaration or Oath (including power of attorney)

NOTE: A newly executed declaration is not required in a continuation or divisional application provided the prior nonprovisional application contained a declaration as required, the application being filed is by all or fewer than all the inventors named in the prior application, there is no new matter in the application being filed, and a copy of the executed declaration filed in the prior application (showing the signature or an indication thereon that it was signed) is submitted. The copy must be accompanied by a statement requesting deletion of the names of person(s) who are not inventors of the application being filed. If the declaration in the prior application was filed under Section 1.47 then a copy of that declaration must be filed accompanied by a copy of the decision granting Section 1.47 status or, if a nonsigning person under Section 1.47 has subsequently joined in a prior application, then a copy of the subsequently executed declaration must be filed. See 37 C.F.R. Section 1.63(d)(1)-(3).

NOTE: A declaration filed to complete an application must be executed, identify the specification to which it is directed, identify each inventor by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and the residence, post office address and country of citizenship of each inventor, and state whether the inventor is a sole or joint inventor. 37 C.F.R. Section 1.63(a)(1)-(4).

NOTE: The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by Section 1.62, except as provided for in Section 1.53(d)(4) and Section 1.63(d). If an oath or declaration as prescribed by Section 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to Section 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in Section 1.17(l) is filed supplying or changing the name or names of the inventor or inventors. 37 C.F.R. Section 1.41(a)(1).

[ ] Enclosed

Executed by

(check all *applicable boxes)*

[ ] inventor(s).
[ ] legal representative of inventor(s). 37 C.F.R. Section 1.42 or 1.43.
[ ] joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.

[ ] This is the petition required by 37 C.F.R. Section 1.47 and the statement required by 37 C.F.R. Section 1.47 is also attached. See item 13 below for fee.

[ ] Not Enclosed.

NOTE: Where the filing is a completion in the U.S. of an International Application, or where the completion of the U.S. application contains subject matter in addition to the International Application, the application may be treated as a continuation or continuation-in-part, as the case may be, utilizing ADDED PAGE FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED.

[ ] Application is made by a person authorized under 37 C.F.R. 1.41 on behalf of *all* the above named inventor(s).

[ ] Showing that the filing is authorized.
(not required unless called into question. 37 C.F.R. Section 1.41(d))

6. Inventorship Statement

WARNING: *If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at the time the last claimed invention was made, should be submitted.*

The inventorship for all the claims in this application are:

[ ] The same.

or

[ ] Not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made,

[ ] is submitted.

[ ] will be submitted.

7. Language

NOTE: *An application including a signed oath or declaration may be filed in a language other than English. An English translation of the non-English language application and the processing fee of $130.00 required by 37 C.F.R. Section 1.17(k) is required to be filed with the application, or within such time as may be set by the Office. 37 C.F.R. Section 1.52(d).*

[X] English

[ ] Non-English

[ ] The attached translation includes a statement that the translation is accurate. 37 C.F.R. Section 1.52(d).

8. Assignment

[X] An assignment of the invention to:

G.I. VIEW LTD.

[ ] is attached. A separate [ ] "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or [ ] FORM PTO 1595 is also attached.

[X] will follow.

[ ] has been recorded at Reel _____, Frame _____ on_____

NOTE: *"If an assignment is submitted with a new application, send two separate letters-one for the application and one for the assignment" Notice of May 4, 1990 (1114 O.G. 77-78).*

WARNING: *A newly executed "STATEMENT UNDER 37 C.F.R. Section 3.73(b)" must be filed when a continuation-in-part application is filed by an assignee. Notice of April 30, 1993, 1150 O.G. 62-64.*

9. **Certified Copy**

Certified copy(ies) of application(s)

Country	Appln. no.	Filed
Country	Appln. no.	Filed
Country	Appln. no.	Filed

from which priority is claimed

[ ] is (are) attached.
[ ] will follow.
[ ] was filed in parent application _____

NOTE: 37 C.F.R. §1.55. Claim for foreign priority.

*"(a) * * *

(1)(i) In an original application filed under 35 U.S.C. 111(a), the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. This time period is not extendable. The claim must identify the foreign application for which priority is claimed, as well as any foreign application for the same subject matter and having a filing date before that of the application for which priority is claimed, by specifying the application number, country (or intellectual property authority), day, month, and year of its filing. The time periods in this paragraph do not apply in an application under 35 U.S.C. 111(a) if the application is:*

(A) A design application; or

(B) An application filed before November 29, 2000.

* * * *

(C) Unless such claim is accepted in accordance with the provisions of this paragraph, any claim for priority under 35 U.S.C. 119(a)-(d) or 365(a) not presented within the time period provided by paragraph (a) of this section is considered to have been waived. If a claim for priority under 35 U.S.C. 119(a)-(d) or 365(a) is presented after the time period provided by paragraph (a) of this section, the claim may be accepted if the claim identifying the prior foreign application by specifying its application number, country (or intellectual property authority), and the day, month, and year of its filing was unintentionally delayed. A petition to accept a delayed claim for priority under 35 U.S.C. 119(a)-(d) or 365(a) must be accompanied by:

(1) The claim under35 U.S.C. 119(a)-(d) or 365(a) and this section to the prior foreign application, unless previously submitted;

(2) The surcharge set forth in § 1.17(t); and

(3) A statement that the entire delay between the date the claim was due under paragraph (a)(1) of this section and the date of the claim was filed was intentional. The Commissioner may require additional information where there is a question whether the delay was intentional."

NOTE: 37 C.F.R. § 1.63 Oath or declaration.

"(a) An oath or declaration filed under § 1.51(b)(2) as a part of a nonprovsional application must:

* * * *

(c) Unless such information is supplied on an application data sheet in accordance with § 1.76, the oath or declaration must also identify:

(2) An foreign application for patent (or inventor's certificate) for which a claim for priority is made pursuant to § 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing."

The foreign application forming the basis for the claim for priority must be referred to in the oath or declaration. 37 C.F. R. § 1.55(a) and 1.63.

NOTE: This item is for any foreign priority for which the application being filed directly relates. IF any parent U.S. application or international Application form which this application claims benefit under 35 U.S.C. § 120 is itself entitled to priority from a prior foreign application, then complete item 18 on the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

10. Fee Calculation (37 C.F.R. Section 1.16)

A. [X] Regular application

CLAIMS AS FILED					
Claims	Number Filed	Basic Fee Allowance	Number Extra	Rate	Basic Fee 37 C.F.R. Section 1.16(a) $770.00
Total Claims (37 C.F.R. Section 1.16(c))	73	-20 =	53 x	$ 18.00	954.00
Independent Claims (37 C.F.R. Section 1.16(b))	3	- 3 =	x	$ 86.00	
Multiple Dependent Claim(s), if any (37 C.F.R. Section 1.16(d))				$290.00	

[ ] Amendment canceling extra claims is enclosed or above.
[ ] Amendment deleting multiple-dependencies is enclosed.
[ ] Fee for extra claims is not being paid at this time.

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims canceled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 C.F.R. Section 1.16(d).

Filing Fee Calculation $ 1,724.00

B. [ ] Design application
($340.00--37 C.F.R. Section 1.16(f))
Filing Fee Calculation $_____

C. [ ] Plant application
($530.00--37 C.F.R. Section 1.16(g))
Filing Fee Calculation $_____

11. Small Entity Statement(s)

[ ] Statement(s) or Written Assertion(s) that this is a filing by a small entity under 37 C.F.R. Section 1.9 and 1.27 is (are) attached.

[ ] Applicant hereby asserts small entity status by paying the small entity filing fee.

NOTE: 37 C.F.R. § 1.27(c) deals with the assertion of small entity status; whether by a written specific declaration thereof or by payment as a small entity of the basic filing fee or the fee for the entry into the national phase and states:

"(c) Assertion of small entity status. Any party (person, small business concern or nonprofit organization) should make a determination, pursuant to paragraph (f) of this section, of entitlement to be accorded small entity status based on the definitions set forth in paragraph (a) of this section, and must, in order to establish small entity status for the purpose of paying small entity fees, actually make an assertion of entitlement to small entity status, in the manner set forth in paragraphs (c)(1) or (c)(3) of this section, in the application patent in which such small entity fees are to be paid.

(1) Assertion by writing. Small entity status may be established by a written assertion of entitlement to small entity status. A written assertion must:

(i) Be clearly identifiable;

(ii) Be signed (see paragraph (c)(20 of this section); and

(iii) Convey the concept of entitlement to small entity status, such as by stating that applicant is a small entity, or that small entity status is entitled to be asserted for the application or patent. While no specific words or wording are required to assert small entity status, the intent to assert small entity status must be clearly indicated in order to comply with the assertion requirement.

(2) Parties who can sign and file the written assertion. The written assertion can be signed by:

(i) One of the parties identified in § 1.33(b) (e.g., an attorney or agent registered with the Office), § 3.73(b) of this chapter notwithstanding, who can also file the written assertion;

(ii) At least one of the individuals identified as an inventor (even though a § 1.63 executed oath or declaration has not been submitted), not withstanding § 1.33(b)(4), who can also file the written assertion pursuant to the exception under § 1.33(b) of this part; or

(iii) An assignee of an undivided part interest, notwithstanding §§ 1.33(b)(3) and 3.73(b) of this chapter, but the partial assignee cannot file the assertion without resort to a party identified under § 1.33(b) of this part.

(3) *Assertion by payment of the small entity basic filing or basic national fee. The payment, by any party, of the exact amount of one of the small entity basic filing fees set forth in §§ 1.16(a), (f), (g), (h), or (k), or one of the small entity basic national fees set forth in §§ 1.492(a)(1), (a)(2), (a)(3), (a)(4), or (a)(5), will be treated as a written assertion of entitlement to small entity status even if the type of basic filing or basic national fee is inadvertently selected in error.*

(i) *If the Office accords small entity status based on payment of a small entity basic filing or basic national fee under paragraph (c)(3) of this section that is not applicable to that application, any balance of the small entity fee that is applicable to that application will be due along with the appropriate surcharge set forth in § 1.16(e), or § 1.16(l).*

(ii) *The payment of any small entity fee other than those set forth in paragraph (c)(3) of this section (whether in the exact fee amount or not) will not be treated as a written assertion of entitlement to small entity status and will not be sufficient to establish small entity status in an application or a patent."*

WARNING: *37 C.F.R. § 1.27(c)(4): "Assertion required in related, continuing, and reissue applications. Status as a small entity must be specifically established by an assertion in each related, continuing and reissue application in which status is appropriate and desired. Status as a small entity in one application or patent does not affect the status of any other application or patent, regardless of the relationship of the applications or patents. The refiling of an application under § 1.53 as a continuation, divisional, or continuation-in-part application (including a continued prosecution application under § 1.53(d)), or the filing of a reissue application, requires a new assertion as to continued entitlement to small entity status for the continuing or reissue application."*

WARNING: *"Small entity status must not be established when the person or persons signing the . . . statement can unequivocally make the required self-certification." M.P.E.P. Section 509.03, 6th ed., rev. 2, July 1996 (emphasis added).*

(complete the following, if applicable)

[ ] Status as a small entity was claimed in prior application _____, filed on_____ from which benefit is being claimed for this application under:

35 U.S.C. Section
- [ ] 119(e) - provisional,
- [ ] 120 - continuation,
- [ ] 121- divisional,
- [ ] 365(c) - PCT,

and which status as a small entity is still proper and desired.

[ ] A copy of the statement or written assertion in the prior application is included.

Filing Fee Calculation (50% of A, B or C above) $_____

NOTE: *A refund based on establishment of small entity status, of a portion of fees timely paid in full prior to establishing status as a small entity may only be obtained if an assertion under § 1.27(c) and a request for a refund of the excess amount are filed within three months of the date of the timely payment of the full fee. The three-month time period is not extendable under § 1.136. 37 C.F.R. § 1.28(a).*

12. **Request for International-Type Search** (37 C.F.R. Section 1.104(d))

(complete, if applicable)

[ ] Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

13. **Fee Payment Being Made at This Time**

[X] Not Enclosed

[X] No filing fee is to be paid at this time and any and all prior fee authorizations are revoked.
(This and the surcharge required by 37 C.F.R. Section 1.16(e) can be paid subsequently.)

[ ] Enclosed

[ ]	Filing fee	$_____
[ ]	Recording assignment ($40.00; 37 C.F.R. Section 1.21(h)) (See attached "COVER SHEET FOR ASSIGNMENT ACCOMPANYING NEW APPLICATION.")	$_____
[ ]	Petition and fee for filing by other than all the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached ($130.00; 37 C.F.R. Sections 1.47 and 1.17(I))	$_____
[ ]	For processing an application with a specification in a non-English language ($130.00; 37 C.F.R. Sections 1.52(d) and 1.17(k))	$_____
[ ]	Processing and retention fee ($130.00; 37 C.F.R. Sections 1.53(d) and 1.21(l))	$_____
[ ]	Fee for international-type search report ($40.00; 37 C.F.R. Section 1.21(e))	$_____

NOTE: 37 C.F.R. Section 1.21(l) establishes a fee for processing and retaining any application that is abandoned for failing to complete the application pursuant to 37 C.F.R. Section 1.53(f) and this, as well as the changes to 37 C.F.R. Section 1.53 and 1.78(a)(1), indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid, or the processing and retention fee of Section 1.21(l) must be paid, within 1 year from notification under Section 53(f).

Total Fees Enclosed $_____

14. Method of Payment of Fees

[ ] Check in the amount of $_____.

[ ] Charge Account No. 12-0425 in the amount of $_____.
A duplicate of this transmittal is attached.

15. Authorization to Charge Additional Fees

WARNING: If no fees are to be paid on filing, the following items should not be completed.

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.

[ ] The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No._____.

[ ] 37 C.F.R. Section 1.16(a), (f) or (g) (filing fees)

[ ] 37 C.F.R. Section 1.16(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims canceled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. Section 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

[ ] 37 C.F.R. Section 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)

[ ] 37 C.F.R. Section 1.17(a)(1)-(5) (extension fees pursuant to Section 1.136(a).

[ ] 37 C.F.R. Section 1.17 (application processing fees)

NOTE: "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under Section 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in Section 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. Section 1.136(a)(3).

NOTE: Section 1.311(b) provides that an authorization to charge the issue fee (§ 1.18) to a deposit account may be filed in an individual application only after the mailing of the notice of allowance. Accordingly, general authorizations to pay fees and specific authorizations to pay the issue fee that are filed prior to the mailing of a notice of allowance will generally not be treated as requesting payment of the issue fee and will not be given effect to act as a reply to the notice of allowance Applicant, when paying the issue fee, should submit a new authorization to charge fees, such as by completing box 6b on the current PTOL-85B form. Where no reply to the notice of allowance is received, the application will stand abandoned notwithstanding the presence of general authorizations to pay fees or a specific authorization to pay the issue fee that were submitted prior to mailing of the notice of allowance. Where an attempt is made to pay the issue fee but an incorrect amount is submitted, § 1.311(b)(1), or where the Office's issue fee transmittal form (currently PTOL-85(B)) is completed by applicant and submitted, § 1.311(b)(2), in reply to a notice of allowance, an exception will be made. Such submissions will operate as a request to charge the issue fee to any deposit account identified in a previously filed (i.e., submitted prior to the mailing of the notice of allowance) authorization to charge fees, and will be allowed to act as payment of he correct issue fee. § 1.311(b). See also the change to § 1.26(b). Notice of September 8, 2000, Fed. Reg. 54603-54683, at 54646 and 54647.

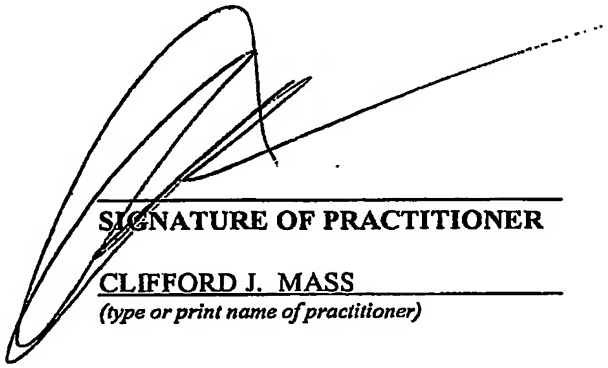
NOTE: 37 C.F.R. Section 1.28(b) requires "Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying, . . issue fee." From the wording of 37 C.F.R. Section 1.28(b), (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

16. Instructions as to Overpayment

NOTE: ". . . Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. Section 1.26(a).

[ ] Credit Account No. _____.

[ ] Refund



SIGNATURE OF PRACTITIONER

CLIFFORD J. MASS
(type or print name of practitioner)

P.O. Address

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Reg. No. 30,086

Tel. No.: (212)708-1890

Customer No.: 00140

[X] **Incorporation by reference of added pages**

(check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED)

[X] Plus Added Pages for New Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed

Number of pages added 8

[ ] Plus added pages deleting names of inventor(s) named on prior application(s) who is/are no longer inventor(s) of the subject matter claimed in this application.

Number of pages added _____

[ ] **Statement Where No Further Pages Added**

(if no further pages form a part of this Transmittal, then end this Transmittal with this page and check the following item)

[ ] This transmittal ends with this page.

Practitioner's Docket No. U 015177-0 *PATENT*

ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED

NOTE: See 37 CFR 1.78.

17. Relate Back

WARNING: If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

(complete the following, if applicable)

[ ] **A separate Preliminary Amendment amends** the specification by inserting, before the first line, the following paragraph:

A. 35 U.S.C. 119(e)

NOTE: 37 C.F.R. § 1.78(a)(4) and (5):

"(4) A nonprovisional application, other than for a design patent, or an international application designating the United States of America may claim an invention disclosed in one or more prior-filed provisional applications. In order for an application to claim the benefit of one or more prior-filed provisional applications, each prior-filed provisional application must name as an inventor at least one inventor named in the later-filed application and disclose the named inventor's invention claimed in at least one claim of the later filed application in the manner provided by the first paragraph of 35 U.S.C. 112. In addition, each prior-filed provisional application must be entitled to a filing date as set forth in § 1.53(c), and the basic filing fee set forth in § 1.16(k) must be paid within the time period set forth in § 1.53(g).

"(5)(i) Any nonprovisional application or international application designating the United States of America claiming the benefit of one or more prior-filed provisional applications must contain or be amended to contain a reference to each such prior-filed provisional application, identifying it by the provisional application number (consisting of series code and serial number).

(ii) This reference must be submitted during the pendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C. 111(a), this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed provisional application. IF the later-filed application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, this reference must also be submitted within the later of four months from the date on which the national state commenced under 35 U.S.C. 371(b) or (f) in the later-filed international application or sixteen months from the filing date of the prior-filed provisional application. These time periods are not extendable. Except as provided in paragraph (a)(6) of this section, the failure to timely submit the reference is considered a waiver of any benefit under 35 U.S.C. 119(e) to such prior-filed provisional application. The time periods in this paragraph do not apply if the later-filed application is:

(A) An application filed under 35 U.S.C. 111(a) before November 29,, 2000; or

(B) A nonprovisional application which entered the national stage after compliance with 35 U.S.C. 371from an international application filed under 35 U.S.C. 363 before November 29, 2000.

(iii) If the later-filed application is a nonprovisional application, the reference required by this paragraph must be included in an application data sheet (§ 1.76), or the specification must contain or be amended to contain such reference in the first sentence following the title."

[X] "This application claims the benefit of U.S. Provisional Application(s) No(s).:

APPLICATION NO(S).:	FILING DATE
_____/ NOT YET KNOWN _____	January 9, 2004
_____/_____	_____
_____/_____	_____

and incorporates the same by reference."

WARNING: 37 C.F.R. § 1.78(5)(iv): "(iv) If the prior-filed provisional application was filed in a language other than English and an English-language translation of the prior-filed provisional application and a statement that the translation is accurate were not previously filed in the prior-filed provisional application or the later-filed nonprovisional application, applicant will be notified and given a period of time within which to file an English-language translation of the non-English-language prior-filed provisional application and a statement that the translation is accurate. In a pending nonprovisional application failure to timely reply to such a notice will result in abandonment of the application."

Language of Prior Filed Provisional Application

(Supply information for <u>each</u> provisional the benefit of which is being claimed)

The above identified prior filed provisional application whose benefit is being claimed

[x] was filed in the English language,

[ ] was filed in a language other than English and an English translation along with a statement that the translation is accurate was filed in the provisional application, or

[ ] was filed in language other than English and an English translation along with a statement that the translation is accurate is filed herewith.

B. 35 U.S.C. 120, 121 and 365(c)

WARNING: The applicable provisions for the time and manner of claiming the benefit of a prior U. S. application filing date are set forth in 37 C.F.R. § 1.78(a)(1) and (2) as follows:.

"(a)(1) A nonprovisional application or international application designating the United States of America may claim an invention disclosed in one or more prior-filed copending nonprovisional applications or international applications designating the United States of America. In order for an application to claim the benefit of a prior-filed copending nonprovisional application or international application designating the United States of America, each prior-filed application must name as an inventor at least one inventor named in the later-filed application and disclose the named inventor's invention claimed in at least one claim of the later-filed application in the manner provided by the first paragraph of 35 U.S.C. 112. In addition, each prior-filed application must be:

(i) An international application entitled to a filing date in accordance with PCT Article 11 and designating

the United States of America; or

(ii) Complete as set forth in § 1.51(b); or

(iii) Entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) and include the basic filing fee set forth in § 1.16; or

(iv) Entitled to a filing date as set forth in § 1.53(b) and have paid therein the processing and retention fee set forth in § 1.21(l) within the time period set forth in § 1.53(f).

(2)(i) Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application or international application designating the United States of America claiming the benefit of one or more prior-filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain a reference to each such prior-filed application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Cross references to other related applications may be made when appropriate (see § 1.14).

(ii) This reference must be submitted during the pendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C.. 111(a), this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed application. If the later-filed application is a nonprovisional application which entered the national stage form an international application after compliance with 35 U.S.C. 371, this reference must also be submitted within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in the later-filed international application or sixteen months from the filing date of the prior-filed application. These time periods are not extendable. Except as provided in paragraph (a)(3) of this section, the failure to timely submit the reference required by 35 U.S.C. 120 and paragraph (a((2)(i) of this section is considered a waiver of any benefit under 35 U.S.C. 120, 121, or 365(c) to such prior-filed application. The time periods in this paragraph do not apply of the later-filed application is:

(A) An application for a design patent;

(B) An application filed under 35 U.S.C. 111(a) before November 29, 2000; or

(C) A nonprovisional application which entered the national stage after compliance with 35 U.S.C. 371 from an international application filed under 35 U.S.C. 363 before November 29, 2000.

(iii) If the later-filed application is a nonprovisional application, the reference required by this paragraph must be included in an application data sheet (§ 1.76), or the specification must contain or be amended to contain such reference in the first sentence following the title.

(iv) The request for a continued prosecution application under § 1.53(d) is the specific reference required by 35 U.S.C. 120 to the prior-filed application. The identification of an application by application number under this section is the identification of every application assigned that application number necessary for a specific reference required by 35 U.S.C. 120 to every such application assigned that application number."

[ ]"This application is a

[ ] continuation

[ ] continuation-in-part

[ ] divisional

of copending

[ ] application number _____ filed on_____
[ ] which is

[ ] International Application _____ filed on _____ , which designated the U.S.,
claims the benefit thereof and incorporates the same by reference."

NOTE: The proper reference to a prior filed PCT application that entered the U.S. national phase is the U.S. serial number and the filing date of the PCT application that designated the U.S.

NOTE: (1) Where the application being transmitted adds subject matter to the International Application, then the filing can be as a continuation-in-part or (2) if it is desired to do so for other reasons then the filing can be as a continuation.

[ ] "The nonprovisional application designated above, namely application _____/_____, filed _____, claims the benefit of U.S. Provisional Application(s) No(s).:

APPLICATION NO(S).: **FILING DATE**

_____/_____ _____
_____/_____ _____
_____/_____ _____.
and incorporates the same by reference"

C. Publication of International Application-Provisional Application

NOTE: 35 U.S.C. 154 Contents and term of patent; provisional rights

(d)(4) REQUIREMENTS FOR INTERNATIONAL APPLICATIONS–

(A) EFFECTIVE DATE–The right under paragraph (1) to obtain a reasonable royalty based upon the publication under the treaty defined in section 351(a) of an international application designating the United States shall commence on the date on which the Patent and Trademark Office receives a copy of the publication under the treaty of the international application, or, if the publication under the treaty of the international application is in a language other than English, on the date on which the Patent and Trademark Office receives a translation of the international application in the English language.

The international application corresponding to the instant application

[ ] was
[ ] was not

published under PCT Article 21(2) in the English language.

[ ] An English translation of the international application is attached.

18. Relate Back—35 U.S.C. 119 Priority Claim for Prior Application

NOTE: 37 C.F.R. § 1.55 Claim for foreign priority.

> *"(a) An applicant in a nonprovisional application may claim the benefit of the filing date of one or more prior foreign applications under the conditions specified in 35 U.S.C. 119(a) through (d) and (f)(, 172, and 365(a) and (b).*
>
> *(1)(i) In an original application filed under 35 U.S.C. 111(a), the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. this time period is not extendable. The claim must identify the foreign application for which priority is claimed, as well as any foreign application for the same subject matter and having a filing date before that of the application for which priority is claimed, by specifying the application number, country (or intellectual property authority), day, month, and year of its filing. The time period in this paragraph does not apply to an application for a design patent.*
>
> *(ii) In an application that entered the national stage from an international application after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and the Regulations under the PCT."*
>
> *(2) The claim for priority and the certified copy of the foreign application specified in 35 U.S.C. 119(b) or PCT Rule 17 must, in any event, be filed before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by the processing fee set forth in § 1.17(i), but the patent will not include the priority claim unless corrected by a certificate of correction under 35 U.S.C. 255 and § 1.323.*

The prior U.S. application(s), including any prior International Application designating the U.S., identified above in item 17B, in turn itself claim(s) foreign priority(ies) as follows:

Country	Appln. no.	Filed
Country	Appln. no.	Filed

The certified copy(ies) has (have)

[ ] been filed on _____, in prior U. S. national (not PCT) application _____, which was filed on_____.

[ ] is (are) attached.
[ ] will follow.

WARNING: The certified copy of the priority application that may have been communicated to the PTO by the International Bureau may not be relied on without any need to file a certified copy of the priority application in the continuing application. This is so because the certified copy of the priority application communicated by the International Bureau is placed in a folder and is not assigned a U.S. serial number unless the national stage is entered. Such folders are disposed of if the national stage is not entered. Therefore, such certified copies may not be available if needed later in the prosecution of a continuing application. An alternative would be to physically remove the priority documents from the folders and transfer them to the continuing application. The resources required to request transfer, retrieve the folders, make suitable record notations, transfer the certified copies, enter and make a record of such copies in the Continuing Application are substantial. Accordingly, the priority documents in folders of international applications that have not entered the national stage may not be relied on. Notice of April 28, 1987 (1079 O.G. 32 to 46).

19. Maintenance of Copendency of Prior Application

NOTE: The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the continuation application. Notice of November 5, 1985 (1060 O.G. 27).

A. [ ] Extension of time in prior application

[ ] A petition and fee extends the term in the pending **prior** application until _____.

[ ] A copy of the petition filed in prior application is attached.

B. [ ] Conditional Petition for Extension of Time in Prior Application

[ ] A conditional petition for extension of time is being filed in the pending **prior** application.

[ ] A copy of the conditional petition filed in the prior application is attached.

C. [ ] No extension is necessary in Prior Application
[ ] Issue Fee paid _____

20. Further Inventorship Statement Where Benefit of Prior Application(s) Claimed

(complete applicable item (a), (b) and/or (c) below)

(a) [ ] This application discloses and claims only subject matter disclosed in the prior application whose particulars are set out above and the inventor(s) in this application are

[ ] the same.

[ ] less than those named in the prior application. It is requested that the following inventor(s) identified for the prior application be deleted:

_____

(type name(s) of inventor(s) to be deleted)

(b) [ ] This application discloses and claims additional disclosure and a new declaration or oath is being filed. With respect to the prior application, the inventor(s) in this application are

[ ] the same.

[ ] the following additional inventor(s) have been added:

_____

(type name(s) of inventor(s) to be added)

(c) [ ] The inventorship for all the claims in this application are

[ ] the same.

[ ] not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made

[ ] is submitted.
[ ] will be submitted.

21. Abandonment of Prior Application *(if applicable)*

[ ] Please abandon the prior application at a time while the prior application is pending, or when the petition for extension of time or to revive in that application is granted, and when this application is granted a filing date, so as to make this application copending with said prior application.

NOTE: According to the Notice of May 13, 1983 (103, TMOG 6-7), the filing of a continuation or continuation-in- part application is a proper response with respect to a petition for extension of time or a petition to revive and should include the express abandonment of the prior application conditioned upon the granting of the petition and the granting of a filing date to the continuing application.

22. Petition for Suspension of Prosecution for the Time Necessary to File an Amendment

WARNING: *"The claims of a new application may be finally rejected in the first Office action in those situations where (1) the new application is a continuing application of, or a substitute for, an earlier application, and (2) all the claims of the new application (a) are drawn to the same invention claimed in the earlier application, and (b) would have been properly finally rejected on the grounds of art of record in the next Office action if they had been entered in the earlier application." MPEP, § 706.07(b).*

NOTE: *Where it is possible that the claims on file will give rise to a first action final for this continuation application and for some reason an amendment cannot be filed promptly (e.g., experimental data is being gathered) it may be desirable to file a petition for suspension of prosecution for the time necessary.*

(check the next item, if applicable)

[ ] There is provided herewith a Petition To Suspend Prosecution for the Time Necessary to File An Amendment (New Application Filed Concurrently)

23. NOTIFICATION IN PARENT APPLICATION OF THIS FILING

[ ] A notification of the filing of this
(check one of the following)

[ ] continuation

[ ] continuation-in-part

[ ] divisional

is being filed in the parent application, from which this application claims priority under 35 U.S.C. § 120.

51129s3

PRESSURE-PROPELLED SYSTEM FOR BODY LUMEN

CROSS-REFERENCES TO RELATED APPLICATIONS

The present application claims the benefit of a US provisional patent application to Gross et al., entitled, "Pressure-propelled system for body lumen," filed on or about January 9, 2004, which is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to a pressure-propelled system, suitable for imaging body lumens, such as the gastrointestinal (GI) tract.

BACKGROUND OF THE INVENTION

Many imaging devices are known for producing medical images of body lumens, such as the gastrointestinal (GI) tract. For example, endoscopy is widely used for observing, photographing tissue, and taking specimens from lesions and the like. In a conventional method of examining a colon using an endoscope, for example, the endoscope is typically manually inserted into the colon. In this manual technique, patients may often complain of abdominal pain and distention because the colon is extended or excessively dilated, thereby necessitating stopping the endoscopic procedure. Furthermore, it is not unusual for the colon to bleed and be accidentally perforated. Insertion of an endoscope through the sigmoid colon and into the descending colon, or through the splenic flexure, the transverse colon, the hepatic flexure or parts affected by previous operations may also be accompanied with difficulty. Because of these reasons, a colonoscopy is typically performed by a relatively small number of skilled practitioners, and the rate of patient pain and discomfort is high.

US Patent 5,337,732 to Grundfest et al., whose disclosure is incorporated herein by reference, describes a robot for performing endoscopic procedures, which includes a plurality of segments attached to each other through an articulated joint. Actuators can move the segments together and apart and change their angular orientation to allow the robot to move in an inchworm or snake-like fashion through a cavity or lumen within a patient. Inflatable balloons around the segments inflate to brace a temporarily stationary segment against the lumen walls while other segments move. A compressed gas line attached to the back segment provides compressed gas to inflate the balloons and optionally to drive the actuators. The lead segment includes a television camera and biopsy arm or other sensors and surgical instruments.

US Patent Application Publication 2003/0168068 to Poole and Young, whose disclosure is incorporated herein by reference, describes a method for lining a body cavity with a liner that contains two chambers by (a) selectively controlling fluid pressure in a first of the chambers so as cause the first chamber to evert and advance into said body cavity, and (b) selectively controlling fluid pressure in a second of said chambers to control the stiffness of the liner.

US Patent Application Publication 2003/0105386 and US Patent 6,485,409 to Voloshin et al., whose disclosures are incorporated herein by reference, describe endoscopic apparatus comprising an inflatable sleeve, wherein inflating the sleeve causes an endoscope to be advanced into the colon.

US Patent Application Publication 2002/0107478 to Wendlandt, whose disclosure is incorporated herein by reference, describes a self-propelled catheter, wherein

pressurizing an everting tube coupled to the catheter advances the catheter into the body.

US Patent 6,702,735 to Kelly, whose disclosure is incorporated herein by reference, describes a device for moving a tool along a passage. The tool is coupled to an inflatable sheath, such that as the sheath is inflated it extends into the passage and carries the tool along.

US Patent 5,259,364 to Bob, et al., whose disclosure is incorporated herein by reference, describes an endoscopic device comprising a flexible eversion tube, wherein inflating the eversion tube causes an endoscope to be advanced into a body cavity.

US Patent 4,403,985 to Boretos, whose disclosure is incorporated herein by reference, describes a catheter containing ports near its distal end through which high pressure fluid is forced to advance and steer the catheter.

SUMMARY OF THE INVENTION

Some embodiments of the present invention provide an imaging system which is propelled by fluid pressure through a body lumen, such as the gastrointestinal (GI) tract. Embodiments of the invention are described hereinbelow with reference to the GI tract, but it is understood that these embodiments are not limited to use in the GI tract, and may be used for other body lumens as well. Unlike the prior art, which may inflate and anchor balloons and similar devices to the GI tract wall in an attempt to overcome the low friction of the GI tract, these embodiments of the present invention utilize the very low friction environment of the GI tract to propel the imaging system, typically with no need for anchoring.

There is thus provided, in accordance with an embodiment of the present invention, a system including a guide member at least partially insertable into a proximal opening of a body lumen, the guide member including a first passageway connectable to a source of fluid pressure, an elongate carrier arranged for sliding movement through the guide member, and a piston head mounted on the carrier, wherein a greater fluid pressure acting on a proximal side of the piston head than on a distal side of the piston head propels the piston head and the carrier in a distal direction in the body lumen.

The system of this embodiment of the invention may have different features. For example, the piston head may be inflatable. The carrier may include a second passageway in fluid communication with the piston head, which may be connected to a source of fluid pressure for inflating the piston head. A vent tube may pass through the piston head,

having an opening distal to the piston head through which fluid may be vented to the outside. An image-capturing device may be mounted on the carrier, such as distal to the piston head. A power supply tube may pass through the carrier and may be connected to the image-capturing device. A fluid supply tube may pass through the carrier and may be connected to a fluid source.

In accordance with an embodiment of the present invention, an auxiliary piston head may be mounted on the carrier proximal to the first-mentioned piston head. The auxiliary piston head, which may be inflatable, may be fixed axially to the carrier at a fixed or variable distance from the first-mentioned piston head. The carrier may include a third passageway in fluid communication with the auxiliary piston head, which may be connected to a source of fluid pressure for inflating the auxiliary piston head.

There is therefore provided, in accordance with an embodiment of the present invention, apparatus for use with a biologically-compatible-fluid pressure source, including:

an elongate carrier, adapted to be inserted through a proximal opening of a body lumen; and

a distal piston head coupled to a distal portion of the carrier and adapted to:

be in direct contact with a wall of the lumen when the carrier is inserted into the lumen,

be advanced distally through the body lumen in response to pressure from the fluid pressure source, and

facilitate passage of fluid out of the lumen from a site within the lumen distal to the piston head.

In an embodiment, an outer surface of the piston head in contact with the wall of the lumen includes a low

friction coating suitable for facilitating sliding of the piston head against the wall of the lumen.

In an embodiment, the lumen includes a gastrointestinal (GI) tract, and the piston head is adapted to be in direct contact with a wall of the GI tract when the carrier is inserted into the GI tract. For example, the GI tract may include a colon, and the piston head may be adapted to be in direct contact with a wall of the colon when the carrier is inserted into the colon.

In an embodiment, the apparatus includes a vent tube, and the piston head is adapted to facilitate the passage of the fluid out of the lumen through the vent tube. For some applications, the vent tube is shaped to define an inner diameter thereof that is between 1 and 3 millimeters. In an embodiment, the vent tube is adapted to passively permit the passage of the fluid out of the lumen. Alternatively, the vent tube is adapted to be coupled to a suction source, whereby to actively facilitate the passage of the fluid out of the lumen. For example, the vent tube may be adapted to be coupled to the suction source such that during operation of the apparatus, a pressure distal to the piston head is between -5 millibar and +15 millibar.

In an embodiment, the piston head is adapted to be inflated so as to attain and maintain the direct contact with the wall of the colon.

For some applications:

(i) the apparatus includes an auxiliary piston head, coupled to the carrier at a position proximal to the distal piston head,

(ii) the auxiliary piston head is adapted to be inflated so as to attain and maintain direct contact with the wall of the colon, and

(iii):

(a) at at least one time while the carrier is within the body lumen, the distal piston head is adapted to be in a state of being already deflated at least in part simultaneously with the auxiliary piston head being already inflated and being advanced distally through the colon in response to pressure from the fluid pressure source, and

(b) at at least one other time while the carrier is within the body lumen, the auxiliary piston head is adapted to be in a state of being already deflated at least in part simultaneously with the distal piston head being already inflated and being advanced distally through the colon in response to pressure from the fluid pressure source.

In an embodiment, the piston head is adapted to be intermittently deflated at least in part, while in the colon, whereby to facilitate the passage of the fluid out of the lumen from the site within the lumen distal to the piston head.

In an embodiment, the apparatus includes a piston-head-pressure sensor, adapted to sense a pressure within the piston head. Alternatively or additionally, the apparatus includes a distal pressure sensor, adapted to sense a pressure within the colon distal to the piston head. Further alternatively or additionally, the apparatus includes a proximal pressure sensor, adapted to sense a pressure within the colon proximal to the piston head. For some applications, one, two, or three of these sensors are provided.

In an embodiment, the apparatus includes:

a pressure sensor, adapted to measure a first pressure associated with operation of the apparatus; and

a control unit, adapted to regulate a second pressure associated with operation of the apparatus responsive to the measurement of the pressure sensor.

For example, the pressure sensor may be adapted to measure a pressure selected from the list consisting of: a pressure distal to the piston head, a pressure proximal to the piston head, and a pressure within the piston head.

In an embodiment, the control unit is adapted to regulate the pressure being measured by the pressure sensor. Alternatively, the control unit is adapted to regulate a pressure other than that being measured by the pressure sensor.

In an embodiment, the piston head is shaped to define a proximal lobe and a distal lobe, the lobes being in fluid communication with each other.

For some applications:

(a) a volume of a first one of the lobes is adapted to decrease in response to a constriction of the colon adjacent thereto,

(b) a volume of a second one of the lobes is adapted to remain constant in the absence of a change in colon diameter adjacent thereto, even if the volume of the first lobe is decreased, and/or

(c) a pressure within the first and second lobes is equal in steady state, regardless of the decrease in volume of the first lobe.

In an embodiment, the piston head is adapted to be at an inflation pressure between 10 and 60 millibar during advancement through the colon (e.g., 20-50 millibar, or 30-45 millibar). Alternatively or additionally, the piston head is adapted to advance through the colon in response to a pressure from the fluid pressure source that is between

30% and 100% of the inflation pressure. For example, the piston head may be adapted to advance through the colon in response to a pressure from the fluid pressure source that is between 50% and 100% of the inflation pressure (e.g., between 50% and 80% of the inflation pressure).

In an embodiment, the piston head is shaped to define a distally-narrowing portion, and is adapted to be inserted into the colon such that a tip of the distally-narrowing portion points in a distal direction when the piston head is in the colon. For some applications, a proximal base of the distally-narrowing portion has a characteristic fully-inflated diameter that is larger than a diameter of at least a part of the colon through which the distally-narrowing portion is adapted to pass, whereby the base of the distally-narrowing portion does not inflate fully when the base is in that part of the colon.

There is further provided, in accordance with an embodiment of the present invention, a method, including:

placing a distal piston head in direct contact with a wall of a body lumen;

applying fluid pressure to the distal piston head to advance the piston head distally through the body lumen; and

facilitating passage of fluid out of the lumen from a site within the lumen distal to the piston head.

In an embodiment, the method includes applying a low friction coating to an outer surface of the piston head intended for contact with the wall of the lumen, the low friction coating being suitable for facilitating sliding of the piston head against the wall of the lumen.

In an embodiment, the lumen includes a gastrointestinal (GI) tract, and placing the piston head includes placing the piston head in direct contact with a wall of the GI tract. In an embodiment, the GI tract includes a colon, and placing

the piston head includes placing the piston head in direct contact with a wall of the colon.

In an embodiment, facilitating the passage of the fluid includes facilitating the passage of the fluid out of the lumen through a vent tube extending from the site distal to the piston head to a site outside of the lumen. For some applications, facilitating the passage of the fluid includes passively permitting the passage of the fluid through the vent tube and out of the lumen. Alternatively, facilitating the passage of the fluid includes actively removing the fluid from the lumen. For example, actively removing the fluid may include applying to the site distal to the piston head a pressure between -5 millibar and +15 millibar.

In an embodiment, placing the piston head in direct contact with the wall includes inflating the piston head to an extent sufficient to attain and maintain the direct contact with the wall of the colon.

In an embodiment, the method includes:

placing an auxiliary piston head proximal to the distal piston head;

inflating the auxiliary piston head to an extent sufficient to attain and maintain direct contact with the wall of the colon;

at at least one time while the distal piston head is within the body lumen, deflating the distal piston head at least in part, such that at a post-distal-piston-head-deflation time when the distal piston head is in a state of being already deflated at least in part, the auxiliary piston head is inflated and advancing distally through the colon in response to the applied fluid pressure; and

at at least one other time while the distal piston head is within the body lumen, deflating the auxiliary piston head at least in part, such that at a post-auxiliary-piston-

head-deflation time when the auxiliary piston head is in a state of being already deflated at least in part, the distal piston head is inflated and advancing distally through the colon in response to the applied pressure.

In an embodiment, facilitating the passage of the fluid out of the lumen includes intermittently deflating the piston head at least in part.

In an embodiment, the method includes sensing a pressure within the piston head, within the colon distal to the piston head, and/or within the colon proximal to the piston head.

In an embodiment, the method includes:

sensing a first pressure associated with performing the method; and

regulating a second pressure associated with performing the method, responsive to sensing the first pressure.

For example, sensing the first pressure may include sensing a pressure selected from the list consisting of: a pressure distal to the piston head, a pressure proximal to the piston head, and a pressure within the piston head.

For some applications, regulating the second pressure includes regulating the first pressure. Alternatively, regulating the second pressure does not include regulating the first pressure.

In an embodiment, inflating the piston head includes inflating the piston head at an inflation pressure between 10 and 60 millibar. Alternatively or additionally, applying the fluid pressure includes setting the fluid pressure to between 30% and 100% of the inflation pressure (e.g., between 50% and 100% of the inflation pressure, or between 50% and 80% of the inflation pressure).

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In an embodiment, inflating the piston head includes inflating the piston head at an inflation pressure between 20 and 50 millibar (e.g., between 30 and 45 millibar).

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

Fig. 1 is a simplified pictorial illustration of a system, constructed and operative in accordance with an embodiment of the present invention, which may be suitable for imaging body lumens, such as the GI tract;

Figs. 2 and 3 are simplified sectional illustrations of distal and proximal portions, respectively, of the system of Fig. 1;

Fig. 4 is a simplified sectional illustration of a carrier of the system of Fig. 1, the section being taken transverse to a longitudinal axis of the carrier, in accordance with an embodiment of the present invention;

Figs. 5A, 5B and 5C are simplified pictorial illustrations of the system of Fig. 1, showing three steps of a mode of operation thereof, wherein inflatable piston heads are inflated and deflated to negotiate obstacles in a body lumen, in accordance with an embodiment of the present invention;

Fig. 6 is a pictorial illustration of a system for use in a body lumen, constructed and operative in accordance with an embodiment of the present invention;

Fig. 7 is a pictorial illustration of an inflated conical balloon, which is adapted for use in accordance with an embodiment of the present invention;

Fig. 8 is a pictorial illustration of a partially-inflated conical balloon in a body lumen, in accordance with an embodiment of the present invention;

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Fig. 9A is a pictorial illustration of the cross-section of a fully inflated portion of a conical balloon, in accordance with an embodiment of the present invention;

Fig. 9B is a pictorial illustration of the cross-section of a partially inflated portion of a conical balloon, in accordance with an embodiment of the present invention; and

Figs. 10A and 10B are pictorial illustrations of a system for use in a body lumen, constructed and operative in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

Reference is now made to Figs. 1-3, which illustrate a system 10, constructed and operative in accordance with an embodiment of the present invention.

As seen best in Fig. 3, system 10 may include a guide member 12, which may be constructed of any medically safe material, such as but not limited to, plastic or metal. Guide member 12 may be formed with a first passageway 14 connected to a source 16 of a pressurized biologically-compatible fluid ("fluid pressure source 16"), such as but not limited to, a source of pressurized air, CO_2 or water. Guide member 12 may be at least partially insertable into a proximal opening 18 (e.g., the rectum) of a body lumen 20 (e.g., the colon). Guide member 12 may include an annular ring 22 for abutting against the proximal opening 18.

Guide member 12 may be formed with a bore 24 through which an elongate carrier 26 may be arranged for sliding movement. An O-ring 28 may be provided for dynamically sealing carrier 26 in its sliding motion relative to the guide member 12. Carrier 26 may be any slender wire, catheter or tube and the like, constructed of any medically safe material, such as but not limited to, a flexible plastic or metal. Carrier 26, including its tip, may be safely deflected and steered through body lumen 20.

A piston head 30 may be mounted on carrier 26. Piston head 30 may be inflatable, and as such may be constructed of any medically safe elastomeric material, such as but not limited to, a bladder or membrane made of polyurethane or silicone rubber, for example. An image-capturing device 32 may be mounted on carrier 26 distal to piston head 30. Piston head 30 is typically fixed to carrier 26 and sealed thereto with O-rings 33, but optionally may be arranged to

slide on carrier 26 up to some distal stop which arrests further distal motion of piston head 30 (image-capturing device 32 may serve as the distal stop, for example). Image-capturing device 32 may comprise, without limitation, a camera (e.g., CCD or CMOS), or alternatively x-ray, ultrasonic, MRI, infrared and/or microwave imaging devices.

Other therapeutic or diagnostic devices may be mounted on or in carrier 26, such as but not limited to, a magnet, drug delivery devices (e.g., via iontophoresis), gene therapy devices and others.

Carrier 26 may include a second passageway 34 in fluid communication with piston head 30, connected to a source of fluid pressure 36 (e.g., pressurized air or water) for inflating piston head 30. For some applications, piston head-inflation fluid pressure source 36 is regulated to maintain a generally constant pressure within piston head 30, regardless of changes of volume of the piston head which occur in response to diameter changes of lumen 20.

A vent tube 38 may pass through or around piston head 30, having an opening 40 distal to piston head 30 through which fluid is ventable to the outside. That is, the proximal end of vent tube 38 vents the fluid past guide member 12 to the outside. For some applications, the proximal end of vent tube 38 may be connected to a suction source (not shown) for sucking fluid through vent tube 38. "Fluid," as used herein, includes liquids and gases.

In an embodiment, vent tube 38 is not used, but instead piston head 30 is temporarily deflated (at least in part), intermittently and/or in response to excess pressure accumulating distal to piston head 30. The temporary deflation of the piston head allows venting of the distal pressure to occur through passageway 14, typically in

conjunction with a temporary decoupling of passageway 14 from fluid pressure source 16.

A power supply tube 42 (e.g., containing electrical wires, fiber optics, etc.) may pass through carrier 26, for connection to image-capturing device 32. Alternatively, the electrical and optical components of image-capturing device 32 may have their own internal power source, with no need for external wiring. Image-capturing device 32 may wirelessly transmit or receive data to or from an external processor (not shown). The components of system 10 may be fully automated with sensors and operate in a closed or open control loop.

A fluid supply tube 44 may pass through carrier 26, which may be connected to a fluid source (not shown), e.g., pressurized water, for cleaning the area near image-capturing device 32, or in combination with the vent tube 38, for cleaning body lumen 20 itself (e.g., the colon).

Experiments carried out by the inventors have shown that the system, as described hereinabove, is able to safely and efficiently advance a colonoscope through the colon of an anesthetized 90 kg pig. In these experiments, elongate carrier 26 was generally radio-opaque, and its motion was tracked in real-time using fluoroscopic imaging. Vent tube 38 was utilized, having an inner diameter of 2 mm. It acted passively (without being connected to a suction source), in order to allow pressure accumulating distal to piston head 30 to be vented to the outside.

In these experiments, a range of operating pressures were examined. The proximal pressure and the pressure within the piston head (intra-head pressure) were controlled, and values were recorded at which satisfactory movement of piston head 30 was observed. In general, for intra-head pressures ranging between 25 and 40 millibar,

movement of piston head 30 was observed when the proximal pressure reached 30-100% of the intra-head pressure.

Typically, when the proximal pressure was below a threshold value, no movement was observed. As the proximal pressure was elevated above the threshold value, piston head 30 advanced through the colon. If the proximal pressure increased significantly above the threshold pressure (e.g., 2-10 millibar above the threshold pressure), then there was pressure leakage between piston head 30 and the wall of lumen 20, and advancement of piston head 30 ceased. In response to such a leak, the proximal pressure was lowered, vent tube 38 allowed the excess accumulated distal pressure to vent to the outside, and movement of piston head 30 recommenced.

In an experiment, an inflatable piston head was formed of thin silicone, and was shaped to have a distal lobe, a proximal lobe, and an intermediate portion connecting the distal and proximal lobes. (See Figs. 10A and 10B.) For an intra-head pressure of 30 millibar, the piston head advanced through the colon when the proximal pressure was maintained between 10 and 20 millibar. During advancement of the piston head, vent tube 38 vented to the outside the pressure that accumulated due to the advancement of the piston head. Leakage around the piston head was observed for proximal pressures greater than about 20 millibar. For an intra-head pressure of 40 millibar, the piston head advanced through the colon when the proximal pressure was maintained between 27 and 30 millibar, both on straight and curved portions of the colon. For straight portions of the colon, proximal pressures of as low as 20 millibar were also sufficient to produce satisfactory movement of the piston head.

Although the rate of advance of the two-lobed piston head was found to vary with the selected pressures, in one

experiment using a thin-walled two-lobed piston head, a total time of 2 minutes passed during the advancing of a colonoscope 1.5 meters into the colon of the pig. In another experiment, using a thick-walled two-lobed piston head, an intra-head pressure of 70 millibar and proximal pressure of 50 millibar resulted in 1.5 meters of colonoscope advancement in 1 minute 41 seconds. Thin-walled piston heads useful for these embodiments of the invention typically have a head wall thickness between 10 and 100 microns, e.g., 50 microns. Thick-walled piston heads useful for these embodiments of the invention typically have a head wall thickness greater than 100 microns, e.g., 150 microns, or 250 microns.

In another experiment, the piston head was formed of polyurethane, and was shaped like a cone, as described hereinbelow with reference to Figs. 7-9. In this experiment, satisfactory advancement of the piston head was obtained at a proximal pressure of 35 millibar, when the intra-head pressure was also 35 millibar. The satisfactory advancement was obtained both on straight and curved portions of the colon.

It is noted that in these experiments, during the time when the intra-head pressure was kept constant, the volume of the piston head changed actively in response to changes in diameter of lumen 20.

Reference is now made to Figs. 1, 2 and 5A-C, which illustrate operation of system 10, in accordance with an embodiment of the present invention. In this embodiment, an auxiliary piston head 46 may be mounted on the carrier proximal to distal piston head 30. Auxiliary piston head 46, which like piston head 30 may be inflatable, may be fixed axially to carrier 26 at a fixed distance from piston head 30. Auxiliary piston head 46 may be sealed with

respect to carrier 26 with O-rings 47. Carrier 26 may include a third passageway 48 in fluid communication with auxiliary piston head 46, connected to a source of fluid pressure 50 for inflating auxiliary piston head 46.

System 10 may be inserted in the rectum with piston heads 30 and 46 initially deflated to facilitate insertion. Distal piston head 30 may then be gently inflated until it expands to the inner wall of body lumen 20. This configuration is shown in Fig. 1. Pressurized fluid (e.g., air) from fluid pressure source 16 may be introduced into the colon through the first passageway 14 of guide member 12. The pressurized fluid creates greater fluid pressure acting on the proximal side of piston head 30 than on the distal side of piston head 30. Opening 40 of vent tube 38 may assist in creating the pressure difference across piston head 30, either passively, or actively via applied suction. This pressure difference propels piston head 30 together with carrier 26 distally into the body lumen (in this example, the colon), as indicated by arrow 60. Image-capturing device 32 may capture images of body lumen 20 as system 10 travels therethrough.

As seen in Fig. 5A, system 10 may eventually reach an obstacle or tight turn, indicated by arrow 62. In such a case, proximal piston head 46 may be inflated and distal piston head 30 may be deflated as shown in Fig. 5B. In this configuration, the pressurized fluid creates greater fluid pressure acting on the proximal side of proximal piston head 46 than on the distal side of proximal piston head 46. This pressure difference propels proximal piston head 46 together with carrier 26 distally, as indicated by arrow 64. This distal movement brings distal deflated piston head 30 past the obstacle, as seen in Fig. 5B. System 10 continues its distal movement in body lumen 20 until proximal piston head

46 reaches the obstacle. At this point, distal piston head 30 may be inflated and proximal piston head 46 may be deflated once again, as shown in Fig. 5C. Once again, the pressurized fluid creates greater fluid pressure acting on the proximal side of distal piston head 30 than on the distal side of distal piston head 30. The pressure difference propels system 10 distally in body lumen 20, and brings proximal deflated piston head 46 past the obstacle. The cycle may be repeated as often as necessary.

Reference is now made to Fig. 6, which illustrates a system 68, constructed and operative in accordance with an embodiment of the present invention. System 68 operates in substantially the same manner as system 10, described hereinabove with reference to Figs. 1-4, in that distal piston head 30 is inflated until it is in contact with body lumen 20, such that a seal between piston head 30 and lumen 20 is formed. Pressurized fluid is then introduced via first passageway 14, producing a larger pressure on the proximal face of piston head 30 than on the distal face of piston head 30, resulting in a net force acting to move piston head 30 distally. A sufficient net pressure force results in distal movement of piston head 30 along with elongate carrier 26 and a tool 79. Tool 79 may comprise an imaging device, a biopsy device, or other apparatus to be used in body lumen 20.

Additionally, for some applications of the present invention, a suction source 78 is coupled to opening 40 via vent tube 38 to provide suction on the distal face of piston head 30 and facilitate the distal movement of piston head 30. Providing suction at opening 40 may also be used in some applications to remove contents of the lumen, such as excess fluid or stool, that are impeding the movement of piston head 30. For some applications, the suction

decreases an accumulation of gas distal to piston head 30 that may be uncomfortable for the patient.

System 68 typically comprises one or more pressure sensors, for example in order to be able to improve or optimize the performance of the system with respect to ease and speed of movement of system 68 through lumen 20. In particular, a first pressure sensor 70 is located proximal to distal piston head 30, in order to determine the pressure acting on the proximal face of distal piston 30. A second pressure sensor 72 is located inside distal piston head 30 to determine the inflation pressure of the distal piston head. A third pressure sensor 74 is located distal to distal piston head 30, to determine the pressure acting on the distal face of piston head 30. The three pressure sensors are coupled to a pressure sensor bus 76, such that the various pressure readings can be sent to an electromechanical or mechanical control unit (not shown), which regulates the different pressures, either automatically or with input from the operator of the system. For some applications, only one of the pressure sensors is included in system 68 (e.g., sensor 70, sensor 72, or sensor 74). For other applications, two of the pressure sensors are included, and one is omitted (e.g., sensor 70, sensor 72, or sensor 74).

In some embodiments of the present invention, satisfactory performance of system 68 is attained by maintaining a pressure on the proximal side of piston head 30 at about 25 millibar gauge, a pressure on the distal side of piston head 30 at about 5 millibar gauge, and a pressure inside piston head 30 at about 20 millibar gauge. These values typically range, as appropriate, between about +10 and +50 millibar, -5 and +15 millibar, and +10 and +60 millibar, respectively.

For some applications, during distal advancement of system 68, the pressure inside piston head 30 is maintained within about 5 millibar of the pressure differential across either side of piston head 30. For example, using the exemplary numbers cited above, a pressured differential across the piston head is 25 millibar - 5 millibar = 20 millibar. By maintaining the pressure inside piston head 30 within 5 millibar of the pressure differential, the pressure inside piston head 30 would generally remain between 15 and 25 millibar. The pressure within piston head 30 is typically maintained near this differential pressure when piston head 30 comprises a flexible but substantially non-elastic material (e.g., a material such as a polyurethane that stretches less than 10% during inflation at less than 50 millibar). For embodiments in which piston head 30 comprises a flexible and elastic material (e.g., a material comprising silicone that stretches more than 10% during inflation at less than 50 millibar), the pressure within piston head 30 is typically greater than the differential pressure.

Other combinations of the distal, proximal, and inside pressures for piston head 30 may be better suited for some applications, and the above numbers are not meant to limit the various operating pressures of embodiments of the current invention. Additionally, for some applications of the present invention, the various pressures acting on piston head 30 are regulated depending on where in the lumen the piston head is located.

To further ease the movement of piston head 30 in lumen 20, piston head 30 comprises a low friction coating, which acts to reduce the friction between piston head 30 and lumen 20. For example, piston head 30 may comprise a Teflon coating or other biocompatible low friction coating.

Additionally or alternatively, the low friction coating comprises a suitable lubricant.

Although Fig. 6 only shows a distal piston head, it is to be understood that the scope of the present invention includes a system comprising a proximal piston head, as shown in Fig. 1, comprising the various pressure control and measuring apparatus described hereinabove with regard to distal piston head 30 of Fig. 6.

Reference is now made to Fig. 7, which illustrates an inflatable piston head 80, constructed and operative in accordance with an embodiment of the present invention. Inflatable piston head 80 comprises an inflatable balloon that has the general form of a body of revolution about the axis formed by elongate carrier 26, wherein the distal end has a smaller diameter than the proximal end. Piston head 80 typically comprises a material that is flexible but substantially inelastic in the range of pressures typically encountered, such that the shape of the piston head is not substantially changed by elastic deformation when the piston head is inflated. Alternatively, piston head 80 comprises a flexible and elastic material. In some embodiments of the present invention, inflatable piston head 80 has the shape of a cone, as shown in Fig. 7. It is noted that whereas a cone is formed by rotating a straight line about an axis of revolution, other shapes for inflatable piston head 80 are formed by rotating curved lines about an axis of revolution. For example, a parabola or circular arc may be used to generate appropriate shapes. In the context of the present patent application and in the claims, all such shapes which become narrower towards their distal end are referred to as having a "distally-narrowing portion."

For some embodiments of the present invention, the base of inflatable piston head 80 is flat. In some other

embodiments, the base of inflatable piston head 80 is curved, wherein the curvature may be either concave or convex.

Fig. 8 shows an application of inflatable piston head 80, in accordance with an embodiment of the present invention. Piston head 80 is typically inserted into lumen 20 in a deflated state and subsequently inflated until appropriate contact is made with the lumen. Due to the shape of inflatable piston head 80, most of a fully-inflated portion 82 of the piston head is not in substantial contact with lumen 20, while a partially-inflated portion 84 of the piston head is in contact with lumen 20, once the piston head is fully pressurized. A good seal between piston head 80 and lumen 20 is typically obtained where fully-inflated portion 82 meets partially-inflated portion 84.

Figs. 9A and 9B show cross-sections of the fully-inflated portion and the partially-inflated portion, respectively, in accordance with an embodiment of the present invention. Resistance of lumen 20 to radial expansion prevents the entire piston head from fully inflating (e.g., as shown in Fig. 7). Thus, partially-inflated portion 84 typically becomes somewhat wrinkled along the length of its contact with lumen 20.

Inflatable piston head 80 is regulated to respond to changes in the diameter of lumen 20 by inflating more as the lumen diameter increases, and by deflating as the lumen diameter decreases, all while maintaining satisfactory contact with the lumen. Since inflatable piston head 80 is typically made of a substantially inelastic material, a relatively modest pressure is needed to inflate the piston head. The inflation pressure is chosen to maintain an appropriate seal between the piston head and the lumen, without undue pressure on the lumen.

Figs. 10A and 10B are pictorial illustrations of a multi-lobed piston head 100 for use in body lumen 20, constructed and operative in accordance with an embodiment of the present invention. Except for differences as noted, apparatus and techniques described hereinabove with respect to other piston heads are typically adapted for use with piston head 100.

Piston head 100 comprises a distal lobe 102 and a proximal lobe 104. Lobes 102 and 104 articulate at an intermediate portion 106. In an embodiment, dimensions of piston head 100 include: (a) a diameter D1 of distal lobe 102, which is substantially equal to the diameter of lumen 20, so as to make a satisfactory seal therewith, (b) a diameter D2 of intermediate portion 106, ranging from about 10% to 40% of D1, and (c) a length D3 of distal lobe 102, ranging from about 3 to 5 cm. It is noted that although multi-lobed piston head 100 only comprises two lobes, the scope of the present invention includes multi-lobed piston heads having more lobes (e.g., 3, 4, or 5 lobes).

Distal and proximal lobes 102 and 104 are in fluid communication with each other through intermediate portion 106. In steady state, as well as at the levels of movement typically encountered during advancement through the colon, the pressure within lobe 102 is substantially the same as the pressure within lobe 104. Thus, passageway 34 and fluid pressure source 36 (Fig. 2) regulate the pressure within both lobes substantially simultaneously. The diameters of the two lobes, however, typically vary independently, in response to changes in the shape of lumen 20 adjacent to each of the lobes. Typically, as with all of the inflatable piston heads described herein, fluid is actively added to or removed from the piston head to maintain a generally constant pressure within the piston head.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing description.

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CLAIMS

1. Apparatus for use with a biologically-compatible-fluid pressure source, comprising:

an elongate carrier, adapted to be inserted through a proximal opening of a body lumen; and

a distal piston head coupled to a distal portion of the carrier and adapted to:

be in direct contact with a wall of the lumen when the carrier is inserted into the lumen,

be advanced distally through the body lumen in response to pressure from the fluid pressure source, and

facilitate passage of fluid out of the lumen from a site within the lumen distal to the piston head.

2. The apparatus according to claim 1, wherein an outer surface of the piston head in contact with the wall of the lumen comprises a low friction coating suitable for facilitating sliding of the piston head against the wall of the lumen.

3. The apparatus according to claim 1, wherein the lumen includes a gastrointestinal (GI) tract, and wherein the piston head is adapted to be in direct contact with a wall of the GI tract when the carrier is inserted into the GI tract.

4. The apparatus according to claim 3, wherein the GI tract includes a colon, and wherein the piston head is adapted to be in direct contact with a wall of the colon when the carrier is inserted into the colon.

5. The apparatus according to claim 4, wherein the apparatus comprises a vent tube, and wherein the piston head is adapted to facilitate the passage of the fluid out of the lumen through the vent tube.

6. The apparatus according to claim 5, wherein the vent tube is shaped to define an inner diameter thereof that is between 1 and 3 millimeters.

7. The apparatus according to claim 5, wherein the vent tube is adapted to passively permit the passage of the fluid out of the lumen.

8. The apparatus according to claim 5, wherein the vent tube is adapted to be coupled to a suction source, whereby to actively facilitate the passage of the fluid out of the lumen.

9. The apparatus according to claim 8, wherein the vent tube is adapted to be coupled to the suction source such that during operation of the apparatus, a pressure distal to the piston head is between -5 millibar and +15 millibar.

10. The apparatus according to claim 4, wherein the piston head is adapted to be inflated so as to attain and maintain the direct contact with the wall of the colon.

11. The apparatus according to claim 10,

wherein the apparatus comprises an auxiliary piston head, coupled to the carrier at a position proximal to the distal piston head,

wherein the auxiliary piston head is adapted to be inflated so as to attain and maintain direct contact with the wall of the colon, and

wherein:

(a) at at least one time while the carrier is within the body lumen, the distal piston head is adapted to be in a state of being already deflated at least in part simultaneously with the auxiliary piston head being already inflated and being advanced distally through the colon in response to pressure from the fluid pressure source, and

(b) at at least one other time while the carrier is within the body lumen, the auxiliary piston head is adapted to be in a state of being already deflated at least in part simultaneously with the distal piston head being already inflated and being advanced distally through the colon in response to pressure from the fluid pressure source.

12. The apparatus according to claim 10, wherein the piston head is adapted to be intermittently deflated at least in part, while in the colon, whereby to facilitate the passage of the fluid out of the lumen from the site within the lumen distal to the piston head.

13. The apparatus according to claim 10, wherein the apparatus comprises a piston-head-pressure sensor, adapted to sense a pressure within the piston head.

14. The apparatus according to claim 10, wherein the apparatus comprises a distal pressure sensor, adapted to sense a pressure within the colon distal to the piston head.

15. The apparatus according to claim 10, wherein the apparatus comprises a proximal pressure sensor, adapted to sense a pressure within the colon proximal to the piston head.

16. The apparatus according to claim 15, wherein the apparatus comprises a piston-head-pressure sensor, adapted to sense a pressure within the piston head.

17. The apparatus according to claim 15, wherein the apparatus comprises a distal pressure sensor, adapted to sense a pressure distal to the piston head.

18. The apparatus according to claim 10, wherein the apparatus comprises:

a pressure sensor, adapted to measure a first pressure associated with operation of the apparatus; and

a control unit, adapted to regulate a second pressure associated with operation of the apparatus responsive to the measurement of the pressure sensor.

19. The apparatus according to claim 18, wherein the pressure sensor is adapted to measure a pressure selected from the list consisting of: a pressure distal to the piston head, a pressure proximal to the piston head, and a pressure within the piston head.

20. The apparatus according to claim 18, wherein the control unit is adapted to regulate the pressure being measured by the pressure sensor.

21. The apparatus according to claim 18, wherein the control unit is adapted to regulate a pressure other than that being measured by the pressure sensor.

22. The apparatus according to claim 10, wherein the piston head is shaped to define a proximal lobe and a distal lobe, the lobes being in fluid communication with each other.

23. The apparatus according to claim 22,

wherein a volume of a first one of the lobes is adapted to decrease in response to a constriction of the colon adjacent thereto,

wherein a volume of a second one of the lobes is adapted to remain constant in the absence of a change in colon diameter adjacent thereto, even if the volume of the first lobe is decreased, and

wherein a pressure within the first and second lobes is equal in steady state, regardless of the decrease in volume of the first lobe.

24. The apparatus according to claim 10, wherein the piston head is adapted to be at an inflation pressure between 10 and 60 millibar during advancement through the colon.

25. The apparatus according to claim 24, wherein the piston head is adapted to advance through the colon in response to a pressure from the fluid pressure source that is between 30% and 100% of the inflation pressure.

26. The apparatus according to claim 25, wherein the piston head is adapted to advance through the colon in response to a pressure from the fluid pressure source that is between 50% and 100% of the inflation pressure.

27. The apparatus according to claim 24, wherein the piston head is adapted to be at an inflation pressure between 20 and 50 millibar during advancement through the colon.

28. The apparatus according to claim 27, wherein the piston head is adapted to be at an inflation pressure between 30 and 45 millibar during advancement through the colon.

29. The apparatus according to claim 28, wherein the piston head is adapted to advance through the colon in response to a pressure from the fluid pressure source that is between 30% and 100% of the inflation pressure.

30. The apparatus according to claim 29, wherein the piston head is adapted to advance through the colon in response to a pressure from the fluid pressure source that is between 50% and 100% of the inflation pressure.

31. The apparatus according to claim 30, wherein the piston head is adapted to advance through the colon in response to a pressure from the fluid pressure source that is between 50% and 80% of the inflation pressure.

32. The apparatus according to claim 10, wherein the piston head is shaped to define a distally-narrowing portion, and is adapted to be inserted into the colon such that a tip of the distally-narrowing portion points in a distal direction when the piston head is in the colon.

33. The apparatus according to claim 32, wherein a proximal base of the distally-narrowing portion has a characteristic fully-inflated diameter that is larger than a diameter of at least a part of the colon through which the distally-narrowing portion is adapted to pass, whereby the base of the distally-narrowing portion does not inflate fully when the base is in that part of the colon.

34. A method, comprising:

placing a distal piston head in direct contact with a wall of a body lumen;

applying fluid pressure to the distal piston head to advance the piston head distally through the body lumen; and

facilitating passage of fluid out of the lumen from a site within the lumen distal to the piston head.

35. The method according to claim 34, comprising applying a low friction coating to an outer surface of the piston head intended for contact with the wall of the lumen, the low friction coating being suitable for facilitating sliding of the piston head against the wall of the lumen.

36. The method according to claim 34, wherein the lumen includes a gastrointestinal (GI) tract, and wherein placing the piston head comprises placing the piston head in direct contact with a wall of the GI tract.

37. The method according to claim 36, wherein the GI tract includes a colon, and wherein placing the piston head includes placing the piston head in direct contact with a wall of the colon.

38. The method according to claim 37, wherein facilitating the passage of the fluid comprises facilitating the passage of the fluid out of the lumen through a vent tube extending from the site distal to the piston head to a site outside of the lumen.

39. The method according to claim 38, wherein facilitating the passage of the fluid comprises passively permitting the passage of the fluid through the vent tube and out of the lumen.

40. The method according to claim 38, wherein facilitating the passage of the fluid comprises actively removing the fluid from the lumen.

41. The method according to claim 40, wherein actively removing the fluid comprises applying to the site distal to the piston head a pressure between -5 millibar and +15 millibar.

42. The method according to claim 37, wherein placing the piston head in direct contact with the wall comprises inflating the piston head to an extent sufficient to attain and maintain the direct contact with the wall of the colon.

43. The method according to claim 42, wherein the method comprises:

placing an auxiliary piston head proximal to the distal piston head;

inflating the auxiliary piston head to an extent sufficient to attain and maintain direct contact with the wall of the colon;

at at least one time while the distal piston head is within the body lumen, deflating the distal piston head at least in part, such that at a post-distal-piston-head-deflation time when the distal piston head is in a state of being already deflated at least in part, the auxiliary piston head is inflated and advancing distally through the colon in response to the applied fluid pressure; and

at at least one other time while the distal piston head is within the body lumen, deflating the auxiliary piston head at least in part, such that at a post-auxiliary-piston-head-deflation time when the auxiliary piston head is in a

state of being already deflated at least in part, the distal piston head is inflated and advancing distally through the colon in response to the applied pressure.

44. The method according to claim 42, wherein facilitating the passage of the fluid out of the lumen comprises intermittently deflating the piston head at least in part.

45. The method according to claim 42, wherein the method comprises sensing a pressure within the piston head.

46. The method according to claim 42, wherein the method comprises sensing a pressure within the colon distal to the piston head.

47. The method according to claim 42, wherein the method comprises sensing a pressure within the colon proximal to the piston head.

48. The method according to claim 47, wherein the method comprises sensing a pressure within the piston head.

49. The method according to claim 47, wherein the method comprises sensing a pressure distal to the piston head.

50. The method according to claim 42, wherein the method comprises:

sensing a first pressure associated with performing the method; and

regulating a second pressure associated with performing the method, responsive to sensing the first pressure.

51. The method according to claim 50, wherein sensing the first pressure comprises sensing a pressure selected from the list consisting of: a pressure distal to the piston head, a pressure proximal to the piston head, and a pressure within the piston head.

52. The method according to claim 50, wherein regulating the second pressure comprises regulating the first pressure.

53. The method according to claim 50, wherein regulating the second pressure does not include regulating the first pressure.

54. The method according to claim 42, wherein inflating the piston head comprises inflating the piston head at an inflation pressure between 10 and 60 millibar.

55. The method according to claim 54, wherein applying the fluid pressure comprises setting the fluid pressure to between 30% and 100% of the inflation pressure.

56. The method according to claim 55, wherein applying the fluid pressure comprises setting the fluid pressure to between 50% and 100% of the inflation pressure.

57. The method according to claim 54, wherein inflating the piston head comprises inflating the piston head at an inflation pressure between 20 and 50 millibar.

58. The method according to claim 57, wherein inflating the piston head comprises inflating the piston head at an inflation pressure between 30 and 45 millibar.

59. The method according to claim 58, wherein applying the fluid pressure comprises setting the fluid pressure to between 30% and 100% of the inflation pressure.

60. The method according to claim 59, wherein applying the fluid pressure comprises setting the fluid pressure to between 50% and 100% of the inflation pressure.

61. The method according to claim 60, wherein applying the fluid pressure comprises setting the fluid pressure to between 50% and 80% of the inflation pressure.

62. A system comprising:

a guide member at least partially insertable into a proximal opening of a body lumen, said guide member

including a first passageway connectable to a source of fluid pressure;

an elongate carrier arranged for sliding movement through said guide member; and

a piston head mounted on said carrier, wherein a greater fluid pressure acting on a proximal side of said piston head than on a distal side of said piston head propels said piston head and said carrier in a distal direction in the body lumen.

63. The system according to claim 62, wherein said piston head is inflatable.

64. The system according to claim 63, wherein said carrier includes a second passageway in fluid communication with said piston head and connectable to a source of fluid pressure for inflating said piston head.

65. The system according to claim 62, further comprising a vent tube passing through said piston head, having an opening distal to said piston head through which fluid is ventable to the outside.

66. The system according to claim 62, further comprising an image-capturing device mounted on said carrier.

67. The system according to claim 66, wherein said image-capturing device is distal to said piston head.

68. The system according to claim 66, further comprising a power supply tube passing through said carrier and connected to said image-capturing device.

69. The system according to claim 62, further comprising a fluid supply tube passing through said carrier and connectable to a fluid source.

70. The system according to claim 62, further comprising an auxiliary piston head mounted on said carrier proximal to the first-mentioned piston head.

71. The system according to claim 70, wherein said auxiliary piston head is fixed axially to said carrier at a fixed distance from the first-mentioned piston head.

72. The system according to claim 70, wherein said auxiliary piston head is inflatable.

73. The system according to claim 72, wherein said carrier includes a third passageway in fluid communication with said auxiliary piston head and connectable to a source of fluid pressure for inflating said auxiliary piston head.

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ABSTRACT

Apparatus is provide for use with a fluid pressure source, including an elongate carrier, adapted to be inserted through a proximal opening of a body lumen, and a distal piston head coupled to a distal portion of the carrier. The piston head is adapted to be in direct contact with a wall of the lumen when the carrier is inserted into the lumen, and to be advanced distally through the body lumen in response to pressure from the fluid pressure source. Additionally, the piston head is typically adapted to facilitate passage of fluid out of the lumen from a site within the lumen distal to the piston head.

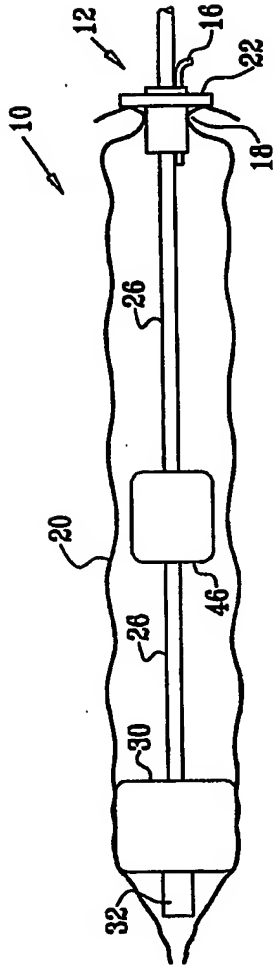
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FIG. 1

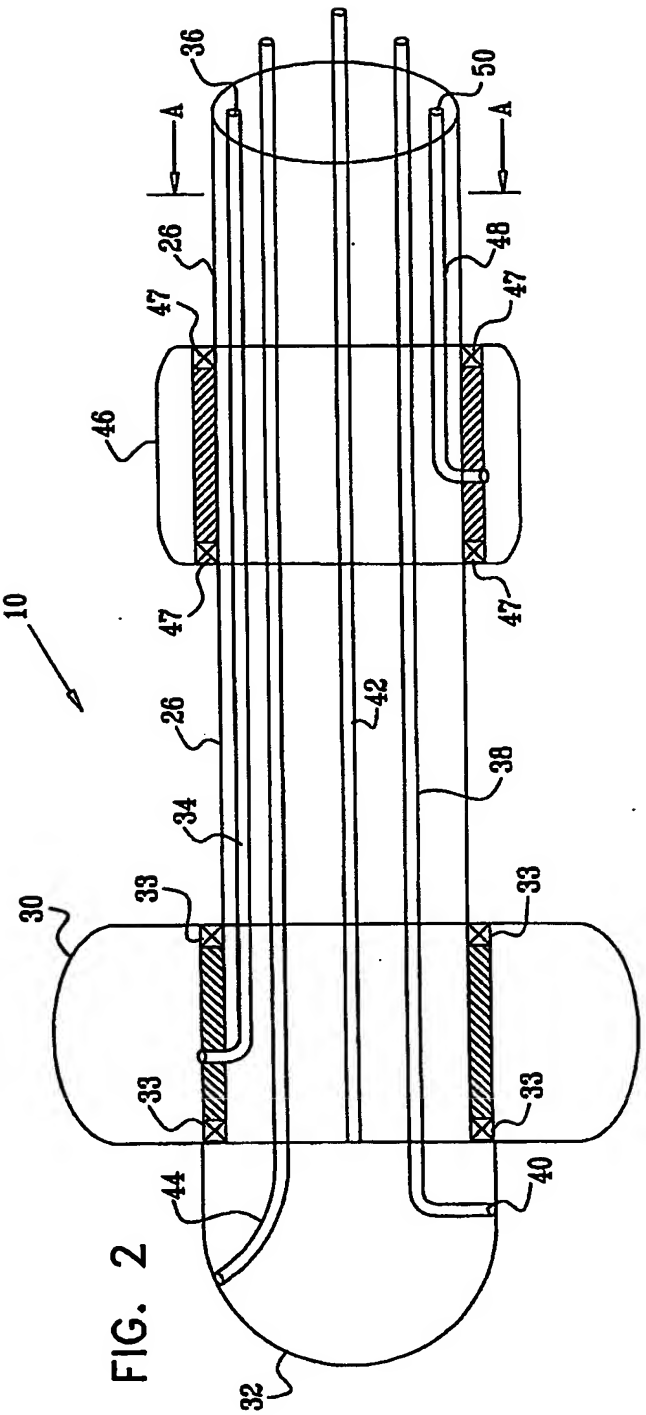
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FIG. 2

FIG. 3

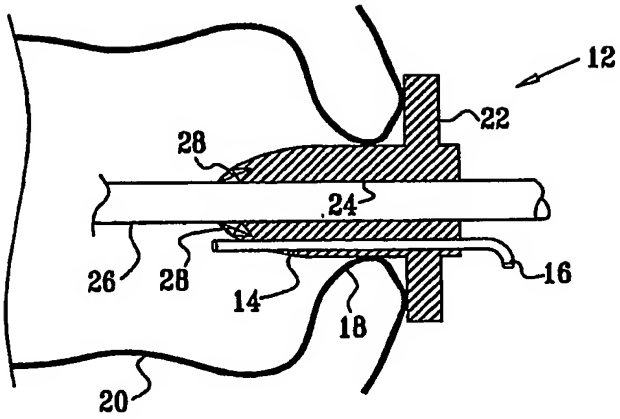


FIG. 4

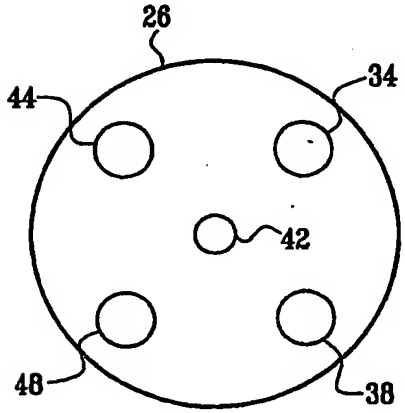


FIG. 5A

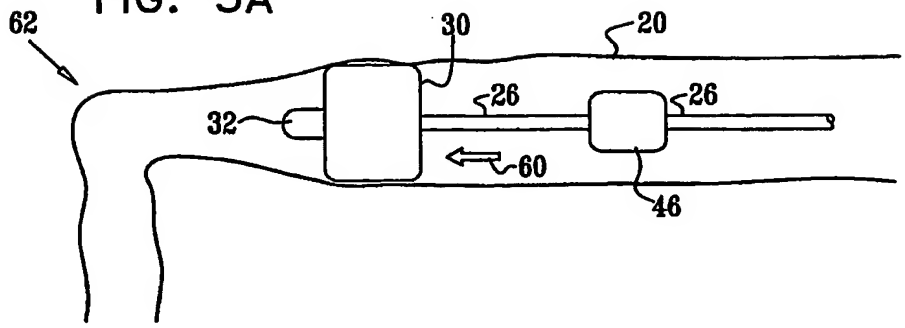


FIG. 5B

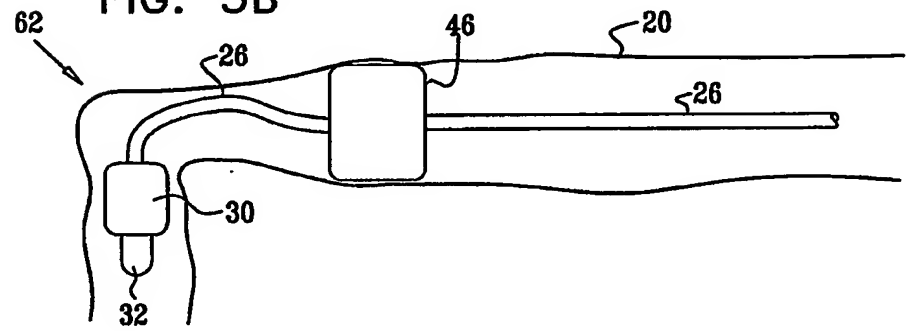


FIG. 5C

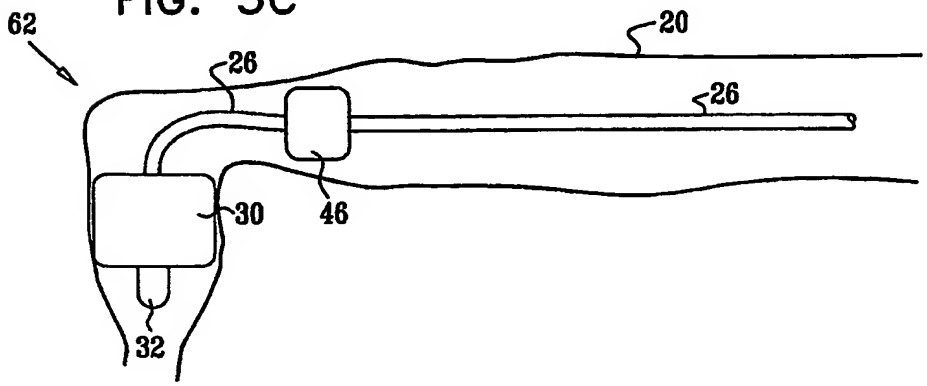
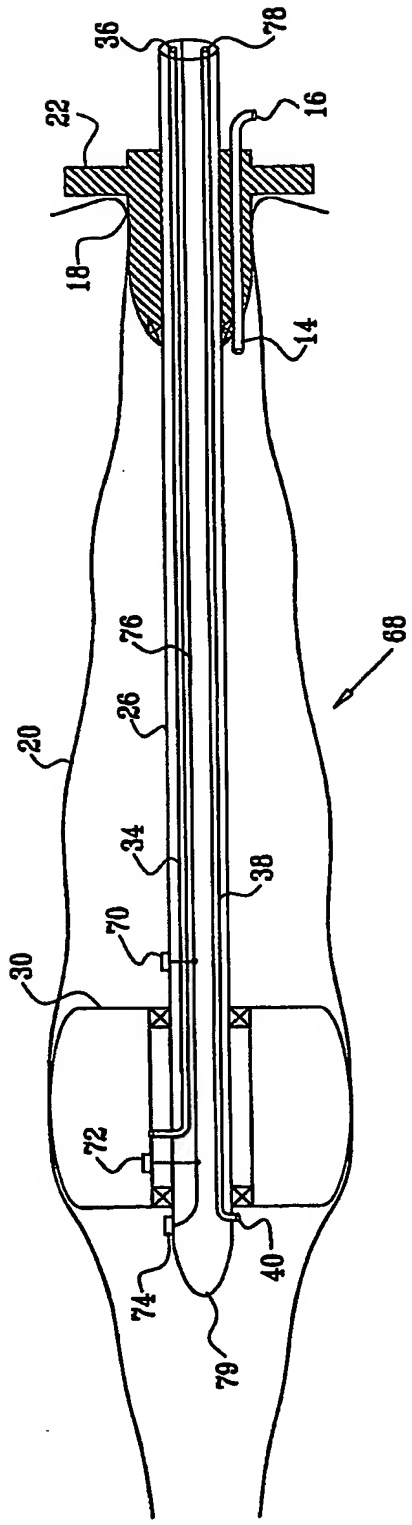


FIG. 6



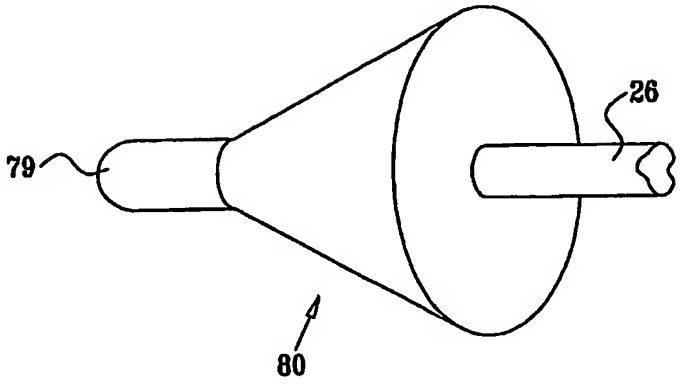


FIG. 7

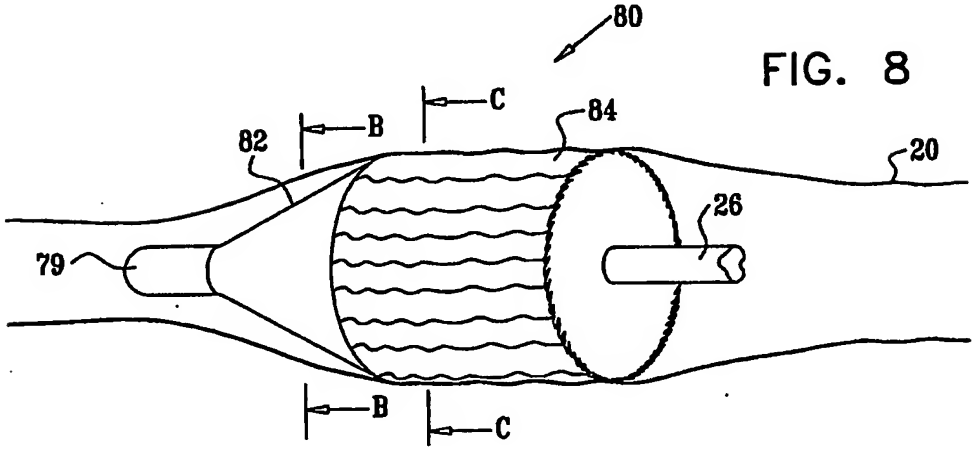


FIG. 8

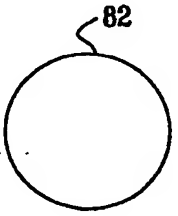


FIG. 9A

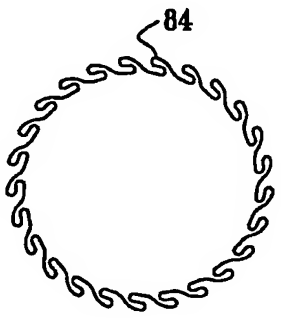


FIG. 9B

FIG. 10A

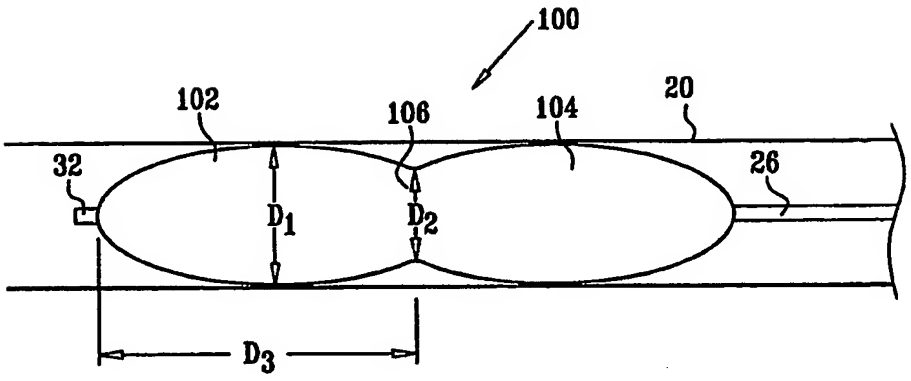
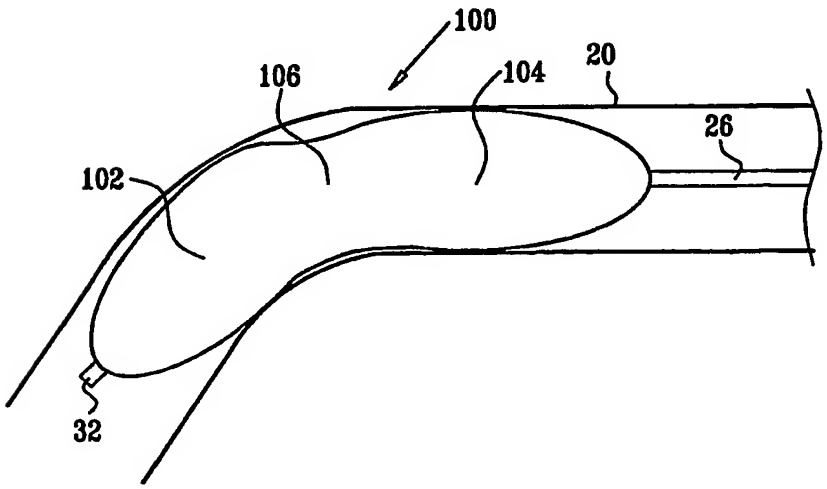


FIG. 10B



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